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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,778	01/14/2004	Jean-Charles Cote	765/12292.6	3697

25545 7590 01/24/2007

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CANADA

EXAMINER
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ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/756,778

Applicant(s)

COTE ET AL.

Examiner

Agnes B. Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3, 9-13, 16-18 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 16-18 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/14/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2006 has been entered.

The amendments to the claims filed on 12/21/2006 have been acknowledged.

#### ***Status of Claims***

Claims 1, 2, 4-8, 14, 15, and 19-21 are cancelled. Claims 3, 9-13, 16-18, and 22 are pending. Claims 3, 16-18, and 22 are currently under examination. Claims 9-13 are withdrawn.

#### ***Priority***

This application claims benefit of 60/448,883 filed on 02/24/2003, which claims foreign priority to CANADA 2,420,153 filed on 12/05/2002.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3, 16-18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because it is not certain what is more than 97% identity to any fragment of Cry31Aa2. Further, there is no SEQ ID NO for Cry31Aa2.

Claim 17 is indefinite, because SEQ ID NO:15 is either Cry31Aa1 or Cry31Aa2. With the limitation in claim 3, which excludes positions 232 to 723 of SEQ ID NO:18, it is concluded that SEQ ID NO:15 has to be Cry31Aa2, which is the SEQ ID NO:8. Thus, the claim is not further limiting.

Claims 16, 18, and 22 are included in this rejection because they depend from independent claim 3 and do not cure the deficiencies of claim 3.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 16-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizuki et al., Parasporin, a Human Leukemic Cell-recognizing Parasporal Protein of *Bacillus thuringiensis*, Clinical and Diagnostic Laboratory Immunology, July 2000, p. 625-634.

The instant invention claims different fragments of Cry31Aa, Cry31Aa1 and Cry31Aa2 that have cytotoxic activity against human cancer cells.

On page 33, paragraph [0087] of the specification, Applicants state that cytotoxic activity of the Cry31Aa1 was due to the cleavage by proteinase K and trypsin (Mizuki et

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al., 2000). Further, the specification states that the amino acids at positions 24, 37, 39, 51, and so on, see paragraph [0087] can be replaced by any other amino acid without abrogating the cytotoxicity of the protein that it constitutes against at least some cancer cells.

Mizuki et al. teach that parasporin of *Bacillus thuringiensis* (CryAa1) exhibited cytocidal activity only when degraded by proteases into smaller molecules, where trypsin and proteinase K activated parasporin, where the activated parasporin showed strong cytocidal activity against some human cancers. See Abstract.

Figure 2 on page 627, shows profiles of native and protease treated parasporal inclusion proteins.

Figure 3 on page 628, shows nucleotide sequence of the parasporin gene, Cry31Aa1 and the deduced amino acid sequence, where N-terminal and five internal amino acid sequences of a wild type 81kDa protein are underlined (where 81 kDa is the full length protein).

On page 630, it is stated that upon treatment with proteinase K, the 81-kDa protein was degraded into four proteins with molecular masses of 66, 58, 56, and 44 kDa, see left column paragraphs; where without protease digestion, inclusion proteins showed no cytocidal toxicity. See page 630, right column, first paragraph.

Further, on page 633, left column, third paragraph, it states that it appeared from the results of immunoblotting and N-terminal sequencing that the 66 kDa and 57-kDa proteins are the partially forms of the 81 kDa protein.

Moreover, Figure 4 on page 629, shows comparison of the deduced amino acid sequences of the five regions in parasporin (Cry31Aa1) with those of the conserved blocks in *B. thuringiensis* endotoxin Cry proteins. See fragments showed as Blocks 1-5, as depicted in the Figure 4.

Analogously, Figure 5 of the instant invention, depicts SEQ ID NO:8 that contains different fragments showed also as Blocks 1-5, that are identical with these taught on page 629, Figure 4 of Mizuki et al.

Further, in the instant invention, SEQ ID NO:8 depicts trypsin activated Cry31Aa2. Therefore, any fragment of the CryAa protein being claimed in claim 3, would have to have more that 98% identity to biologically active fragments, where the biologically active fragments are not active unless clipped, as taught in Mizuki et al.

Claims 16-18 and 22 are included in this rejection because they depend from rejected independent claim 3 and do not cure the deficiencies in claim 3.

#### ***New Matter Rejection***

Claims 3, 16-18, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 3, Applicants refer to an isolated Cry31Aa polypeptide fragment that comprises a sequence having at least 97% identity (*an undefined fragment according to*

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examiner) with the Cry31Aa2 polypeptide fragment where the polypeptide does not consist of the Cry31Aa1 amino acid sequence fragment as set forth at positions 232 to 723 of SEQ ID NO:18.

Examiner reviewed the specification for the support of claim 3, as currently amended, where different fragments of the polypeptides are claimed, and examiner did not find any support in the specification for the different fragments claimed in claim 3. Therefore, the amended claim 3 contains a new matter that is not supported in the specification as originally filed.

Claims 16-18 and 22 are included in this rejection because they depend from rejected independent claim 3 and do not cure the deficiencies.

Examiner's notes regarding art of interest:

1. 100% identity to the SEQ ID NO:8 is disclosed in Jung et al., "83-kDa crystal protein gene from a novel autoagglutinable, nonserotypeable strain of bacillus thuringiensis," Submitted FEB 2002 to the EMBL/GenBank/DDBJ databases.

2. 96.6% identity to the SEQ ID NO:8 is disclosed in Mizuki et al., "Parasporin, a human leukemic cell-recognizing parasporal protein of Bacillus thuringiensis," Clin. Diagn. Lab. Immunol. 7:625-634 (2000).

**Conclusion**

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



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PRIMARY EXAMINER